



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,831	07/11/2001	Chih-Ming Chen	141-201	3745

7590

05/28/2003

James V Costigan
Hedman Gibson & Costigan
1185 Avenue of the Americas
New York, NY 10036-2601

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 05/28/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/763,831

Applicant(s)

CHEN ET AL.

Examiner

Susan Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-30 is/are pending in the application.
- 4a) Of the above claim(s) 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Request for The Extension of Time, Amendment and Information Disclosure Statement filed 03/28/03.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03/28/03 was filed after the mailing date of the Office Action on 09/24/02. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

Newly submitted claims 28-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: newly submitted method claims were not introduced in the original filed claims; the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,174,548 ('548). Although the conflicting claims are not identical, they are not patentably distinct from each other because '548 claims a stable pharmaceutical composition consisting essentially of omeprazole core and an enteric coating layer without a separating layer (sub-coating layer). Lysine and arginine as an alkaline material are found in claims 1 and 2. Surface active agent is found in claim 4. Enteric coating agent is found in claim 3. Although '548 does not limit to pellet formulation, tablet and pellet are suitable oral useful in pharmaceutical art. Therefore, the skilled artisan would expect a similar stable pharmaceutical composition from the use of the instant invention give the claims of '548. There are no unusual and/or unexpected results, which would rebut prima facie obviousness.

Claims 12-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, and 14 of U.S. Patent No. 6,096,340 ('340). Although the conflicting claims are not identical, they are not patentably distinct from each other because '340 claims a stable pharmaceutical composition consisting essentially of omeprazole surrounding a core and an enteric coating layer. Surface active agent is found in claim 7. Enteric coating agent is found in claim 4. Although '340 does not limit the alkaline agent to arginine or lysine, the generic term alkaline agent in claim 1 of '340 permits the use of amino acid, such as arginine or lysine. Therefore, the skilled artisan would expect a similar stable pharmaceutical composition from the use of the instant invention give the claims of '548. There are no unusual and/or unexpected results, which would rebut prima facie obviousness.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chong Kun Dang Korean Patent application 92-17571 (Dang).

Dang teaches an oral pharmaceutical composition in the form of pellet or tablet comprising a core directly coated with an enteric coating (pages 375). The core contains omeprazole; amino acid, such as lysine or arginine; disintegrants; binder;

Art Unit: 1615

lubricant; and the like (page 375). The coating contains eudragit, cellulosic polymer, copolymer, talc, wax, and plasticizer (examples, and pages 382-383). Dang does not specifically teach the claimed amount of alkaline agent. However, Dang teaches the use of a small to sufficient quantities of amino acid (lysine or arginine), which are safe to human body and a high degree of stability (page 375 2nd paragraph). Besides, the ratios of amino acid to omeprazole taught by Dang are similar to the ratios disclosed in applicant's specification. Therefore, it would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable amount of amino acid to obtain the claimed invention, because Dang teaches the advantageous results in the use of a small to sufficient quantities of amino acid that are safe to human body to obtain a stable omeprazole formulation without the need of a sub-coating layer.

Claims 12-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Odidi et al. US 6,296,876, in view of Kim KR 9208161B (abstract only).

Odidi teaches pharmaceutical formulation comprising core, at least one sub-coating layer, and an enteric coating layer (column 2). The core comprising omeprazole mixed with disintegrants, stabilizers, fillers, acid sequestering substance, and excipients (column 3, lines 23-52). Enteric coating contains hydroxypropylmethyl cellulose phthalate and talc (column 4, lines 30-35, and examples). The formulation can be in the form of tablet or pellet (column 4, lines 16-19). Odidi does not specifically teach arginine or lysine as stabilizers, fillers, acid sequestering substance, or excipients in the core.

Kim teaches oral dosage form comprising core including, omeprazole mixed with stabilizing agent, such as lysine or histidine (abstract). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify the pharmaceutical formulation of Kim using lysine as a stabilizing agent in view of the teaching of Kim because the references teach the advantageous results in the use of oral dosage form of omeprazole. The unexpected result would be an omeprazole oral dosage form having excellent resistance to dissolution in acid media, and having good stability during long-term storage.

It is noted that the cited references containing a sub-coating layer. However, absent showing criticality, the absent of a sub-coating layer does not impart patentably distinct (see *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965) (Omission of additional framework and axle which served to increase the cargo carrying capacity of prior art mobile fluid carrying unit would have been obvious if this feature was not desired.); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (deleting a prior art switch member and thereby eliminating its function was an obvious expedient). Furthermore, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps, and those that do not materially affect the basic and novel characteristic of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461. For search and examination purposes, absent a clear indication in the specification of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ at 1355 ("PPG could have defined the scope of the phrase consisting

Art Unit: 1615

essentially of for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”). *When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Response to Arguments

Applicant's arguments filed 03/28/03 have been fully considered but they are not persuasive.

Applicant argues that Odidi teaches away from the presently claimed invention because it teaches the additional step of inserting a separating layer between the core and the enteric coat, which is expressly disclaimed by the present claims. However, applicant has not provide any data showing that the present of the sub-coating layer is detrimental to the desirability of obtaining a stable composition. Applicant's attention is drawn to column 2, lines 56-63, where Odidi teaches the formulation has a good stability during long term storage.

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps, and those that do not materially affect the basic and novel characteristic of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190

USPQ 461. For search and examination purposes, absent a clear indication in the specification of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ at 1355 ("PPG could have defined the scope of the phrase consisting essentially of for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). *When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Applicant argues that the addition of Kim abstract to the Odidi does not lead an individual of ordinary skill in the art to arrive at the claimed invention, because Kim merely teaches a stable omeprazole formulation with a sub-coating layer. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 03/28/03 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600